

REMARKS

The Applicant acknowledges the Office Action, a Final Rejection, of March 10, 2010, with appreciation. The Office indicates that Claims 38-40 and 43-59 are pending in the application, of those, Claims 54-58 are withdrawn from consideration. Claims 38-40, 43-53 and 59 are pending and further considered on the merits.

With regard to the Office exposition of claim pendency above, the Applicant wishes to clarify for the record that Claims 22-40, 43-59 are pending in the instant application, of those, Claims 22-37 and 54-58 are withdrawn from consideration. The Applicant respectfully requests the Office acknowledgement of all claims pending in the instant application.

ANTICIPATION UNDER 35 U.S.C § 102(b):

To begin, the Office maintains the rejection of Claims 38-40, 43-53 and 59 under 35 U.S.C § 102(b) as being anticipated over the disclosure of Hutchens (WO 98/59360, published December 30, 1998). The Office finds that Hutchens discloses a method of retentate chromatography for resolving analytes in a sample. The Office points to disclosure in Hutchens, specifically at page 44, lines 12-32 alleging that the "mixed functionality adsorbents" disclosed in Hutchens anticipate the instantly claimed carriers comprising at least two different groups capable of binding to a substrate. Moreover, the Office points to disclosure in Hutchens, and alleges that Hutchens discloses every element of generic Claim 38 and dependent claims. The Office concludes that Hutchens anticipates the instantly claimed invention.

The Applicant understands that to make out a rejection for anticipation, each claim element must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference.

The Applicant rebuts the Office conclusion that Hutchens anticipates the instant claims on the basis that Hutchens does not disclose every element of the claims and in the claimed arrangement.

Moreover, Hutchens, does not disclose step (b) of generic Claim 38, drawn to a method for the selectively, at least bivalent binding of a substrate having at least two different groups. Accordingly, it is submitted that Claim 38, and the dependent claims, is novel over the disclosure of Hutchens.

It is the position of the Office that Hutchens, at page 30, lines 19 to 30, discloses step (b) of generic Claim 38. Step (b) of generic Claim 38 recites:

(b) the at least two different groups capable of binding in step (ii) are inserted into a polymer via at least two identical or different functional groups of the polymer, whereby a polymer is formed which is derivatized with said groups,

The Applicant submits that Hutchens discloses polymeric adsorbents wherein groups in polymers may be derivatized. The specific disclosure in Hutchens at page 30, lines 23-25 reads:

*"Also, the **terminal** functional groups in the polymers can be reacted so as to chemically derivatize them to varying degrees with different affinity reagent (e.g., -NH₃, **or** -COO⁻)."* (**emphasis added**)

As outlined below, step (b) of generic Claim 38 differs in at least two aspects from the highlighted disclosure in Hutchens.

Hutchens discloses that the **terminal** functional groups of the polymers are reacted with an affinity reagent. It follows from the above recited section of Hutchens that, in fact, each polymer chain can only have **one terminal functional group**, because the second terminal of the polymer is attached to the substrate. (See page 30, lines 21-23 of Hutchens).

In contrast thereto, generic Claim 38 of the subject application requires that the at least two different groups capable of binding are inserted into the polymer “*via at least two identical or different functional groups of the polymer*” at step (b) of Claim 38.

Furthermore, Hutchens does not disclose that the polymer disclosed therein indeed comprises “*two different groups capable of binding*” as instantly claimed in generic Claim 38 at step (b). Hutchens discloses that the polymer (with only one terminal group) may be derivatized to varying degrees with different affinity agents, which reagents may be selected from any number of affinity reagents. In this regard, this understanding is confirmed by the disclosure at page 30, line 25 in Hutchens of the use of $\text{-NH}_3\text{-}$ or COO^- . Thus, Hutchens does not disclose a polymer comprising “*two different groups capable of binding*” as instantly claimed.

Moreover, the Applicant submits that Hutchens does not enable a polymer having at least two identical or different terminal functional groups, which may be reacted in a suitable manner with different affinity reagents in order to insert at least two different groups capable of binding into the polymer according to step (b) of generic Claim 38, without undue experimentation. Accordingly, Hutchens may not be considered to be prior art as set forth below.

Applicant has already discussed that Hutchens does not disclose:

- a specific polymer having at least two identical or different terminal functional groups, nor
- a specific precursor molecule for the preparation of such polymer, nor
- specific terminal functional groups to be reacted with an affinity reagent, nor
- a specific affinity reagent which is suitable to be reacted with the not further specified groups of the not further specified polymer.

Hutchens' reference to polymeric adsorbents which are provided by attaching a precursor molecule to the substrate is not sufficient disclosure of a suitable

precursor molecule which, after polymerization, results in a polymer having at least two identical or different terminal functional groups. The Hutchens reference to an affinity reagent with e.g. $-NH_3$, or $-COO^-$ is also not sufficient disclosure of a suitable affinity reagent to be reacted with the non-specified terminal functional groups of the not further specified polymer. Accordingly, the Hutchens disclosure does not enable the person skilled in the art to perform the reaction as required by step (b) of generic Claim 38.

The Applicant is guided by extensive case law which states that, "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). Furthermore, the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

Moreover, the Applicant notes that a reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

Since the reaction as disclosed by Hutchens cannot be performed without undue experimentation with respect to the selection of a suitable precursor molecule, with respect to the polymer which is formed after polymerization of the precursor molecule and which has to provide for suitable terminal functional groups, with respect to the selection of suitable affinity reagent(s) and the reaction conditions for performing the reaction between the terminal functional groups and the affinity reagent, and since one of ordinary skill in the art could not have combined the publication's description of the invention with his [or her] own knowledge to make the

claimed invention, it is submitted that the Office has not made out the rejection for anticipation over the disclosure of Hutchens. The Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

The Office further considers the disclosure at page 44, line 12 to 32 of Hutchens to anticipate steps (a), (b), and (i) of generic Claim 38, based on alleged disclosure of mixed functionality adsorbents for an improved resolution of the analyte of interest compared to undesired components. The mixed functionality adsorbents are described in Hutchens as exhibiting hydrophobic interactions and ionic interactions, or hydrophobic interactions and the ability to form coordinate covalent bonds. Hutchens explains that, "... it is possible to utilize the plurality of binding characteristics probed by the combination of different adsorbents with respect to a single sample and thereby bind and detect a wider variety of different analytes." (See Hutchens at page 29, lines 28-31, emphasis added).

However, Hutchens is silent with respect to methods for the preparation of mixed functionality adsorbents. In turn, for the same reasons as outlined above, Hutchens does not provide sufficient disclosure to allow the preparation of such adsorbents without undue experimentation. Since one of ordinary skill in the art could not have combined the Hutchens description with his [or her] own knowledge to make the claimed invention, the Applicant submits that Hutchens does not anticipate steps (a), (b), (i) and step (ii), which step (ii) is interrelated with the afore-mentioned steps, of generic Claim 38.

The Applicant submits that Hutchens does not disclose step (i) of generic Claim 38. Step (i) of the instantly claimed method requires that at least two groups capable of binding to a sorbent are determined from the substrate. Hutchens is silent with respect to determining at least two groups from the substrate.

Furthermore, the Applicant submits that the mixed functionality adsorbents of Hutchens are merely speculative; this is confirmed by the examples in Hutchens. Hutchens does not disclose one example in which a mixed functionality adsorbent is employed. With respect to Examples B (page 89), or A (page 90) of Hutchens, the

use of a plurality of different adsorbents is disclosed. The Office attention is drawn to the fact that the various adsorbents disclosed therein are not mixed functionality adsorbents but rather a combination of different mono- functionality adsorbents in which each are used at an individual spot of an array. Hutchens teaches the use of a combination of different adsorbents.

The instant claims are distinguished over the disclosure in Hutchens, in part, for the fact that the instant claims are drawn to respectively applying at least two groups capable of binding the substrate to one respective carrier and are inserted into a polymer via at least two identical or different functional groups of the polymer, as recited in generic Claim 38. Thus, Hutchens does not anticipate the instant claims drawn to a method for selectively at least bivalent binding of a substrate having at least two different groups capable of binding to at least one sorbent as instantly claimed. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully solicited.

* * * * *

Accordingly, entry of the present Response After Final into the record of this application and swift and favorable action on the merits thereof, are respectfully solicited.

It should be apparent that the undersigned has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call the below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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